

Foreword: OSHA requires fit testing for all employees who are required to wear tight-fitting face piece masks. To ensure that MEGATECH SCIENTIFIC M9 SERIES N95 Pouch-Style Masks provide the intended level of protection, every wearer should receive training. This includes demonstrations and practice time on how to properly don the mask and to determine if it fits correctly.

1. Directions for Proper Donning

Proper donning of a M9 SERIES N95 Pouch-Style Mask may feel a little awkward at first, but it will become easier with repeated applications. The following instructions should be followed when donning this product (see below and enclosed poster for clarification):

Steps

Figures

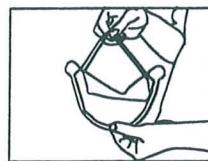
1.1. Check the mask and ensure the nose clip (hard thin piece) is on top.



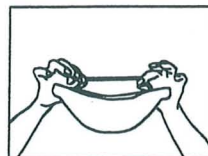
1.2. Open up the upper and lower lips of the mask with your thumbs.



1.3. Pull out the headband with your thumb and index fingers.



1.4. Hold the bands with both hands.



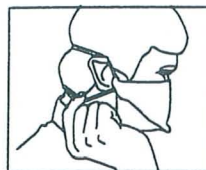
1.5. Place the bands over the head above the ears.



1.6. Hold both ends of the mask and pull it over to cover the nose and the mouth.



1.7. Pull one of the headbands to let it rest below the ears.



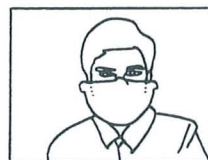
1.8. Press the nose clip to conform to the shape of the nose and face.



1.9. Run your finger across the upper and lower lips of the mask to ensure it is properly set against the face.



1.10. Breathe to check. If there is any substantial leakage, change to a new mask and proceed with the above steps. If not, proceed to wear.



2. Directions for User Seal Checking

To ensure M9 SERIES N95 Pouch-Style Masks are providing the intended level of protection, a User Seal Check must be conducted each and every time they are worn.

To User Seal Check a mask, the wearer should forcefully inhale and exhale several times. The mask should collapse slightly upon inhaling and expand upon exhaling. The wearer should not feel any air leaking between his/her face and the mask. This is the sign of a good facial fit and a successful User Seal Check.

If the mask does not collapse and expand OR if air is leaking out between the wearer's face and the mask, then this is NOT a good facial fit. The wearer should adjust the mask until the leakage is corrected and he/she is able to successfully User Seal Check the mask.

Note: User Seal Checking is NOT a substitute for Fit Testing. User Seal Checking is a simple procedure intended to help the wearer verify that he/she has properly donned the mask. Fit Testing is designed to determine the appropriate size mask for each wearer. Fit Testing should be conducted at least annually as required by OSHA. Your facility's mask protection program may require more frequent Fit Testing.

3. Tips for Achieving a Good Fit

If the wearer is having a problem successfully user seal checking the mask, he/she should try the following tips:

- 3.1. Use a mirror while adjusting the mask.
- 3.2. Ask someone to look for hair or earrings that might be caught in the seal.
- 3.3. Make sure the headbands are positioned properly. It is especially important that the top headband is on the crown of your head, as it is designed to hold the bottom of the mask snug against your chin.

Note: It is important to stress to the wearer that:

- The mask must be User Seal Checked each and every time it is donned, and
- He/she should not proceed with activities until a successful User Seal Check has been completed.

4. Qualitative Fit Testing Protocol

The qualitative Fit Testing protocol consists of two parts: a Threshold Check and a Fit Test. The Threshold Check determines the subject's ability to taste a weak solution of the challenge agent. The Fit Test uses the full strength solution to verify that the wearer can achieve an acceptable facial fit with the mask. A medical evaluation to assess the ability to wear a mask should be conducted prior to fit testing or mask use.

The following items are not included in this Kit but should be available to assist in Fit Testing:

- Covered pitcher or container of water and drinking cups (or a nearby water fountain)
- Disposable towels / napkins or baby wipes
- Stop watch or wrist watch with a second hand
- Adequate supply of the mask style your facility will be using
- Training files or other record-keeping system your facility will be using

Note: This Kit contains saccharin-based Threshold Check and Fit Test solutions. The same protocol, however, can be followed using BITREX[®] (extremely bitter taste) as the challenge agent. Both saccharin and BITREX[®] are OSHA-accepted challenge agents.

Supplies of both saccharin and BITREX[®] are available at a nominal charge by calling your local distributor.

4.1 Preparation

4.1.1. Pour the contents of Threshold Check Solution into the Threshold Check nebulizer. Prepare the Fit Test nebulizer with the Fit Test Solution in the same manner.

4.2.2. Assemble the hood by pressing the VELCRO[®] strips together and fitting the bouffant cap over the top, securing the seam of the cap under the tabs on the hood.

4.2.3. The Fit Test protocol should be explained to the test subject prior to testing. The test subject should not eat, chew gum, or drink anything but water for at least 15 minutes prior to the test.

4.2.4. Record the name of the test subject, type of mask, brand and size of mask, and date of the test.

4.2 Threshold Check Procedure

4.2.1. Have the test subject put on the hood without a mask.

4.2.2. Instruct the subject to breathe through his/her mouth with tongue extended.

4.2.3. Instruct the subject to immediately report when the challenge agent is tasted.

4.2.4. Insert the nozzle of the Threshold Check nebulizer into the hole at the front of the hood and squeeze the bulb firmly ten times. The nozzle should be directed away from the nose and mouth of the person. (If the person reports a taste during this process, stop squeezing. Record "10" as the number of squeezes required, regardless of when the person reported the taste.)

4.2.5. If the subject has not tasted the solution, administer another 10 squeezes. (If the person reports a taste during this process, stop squeezing. Record "20" as the number of squeezes required, regardless of when the person reported the taste.)

4.2.6. If the subject has not tasted the solution, administer another 10 squeezes and ask again if they have tasted the solution. (If the person reports a taste during this process, stop squeezing. Record "30" as the number of squeezes required, regardless of when the person reported the taste.)

4.2.7. If no taste has been detected, and if saccharin is being used, then the subject should be tested with the alternative BITREX[®] solution using these same procedures. If the subject is unable to taste either saccharin or BITREX[®], then the subject cannot be tested using this protocol. Instead, quantitative Fit Testing is suggested.

4.2.8. Remove the hood and allow the subject to rinse his/her mouth with water and wipe his/her face. The subject should not proceed to the Fit Test until the taste of the challenge agent has been allowed to clear, which usually takes several minutes.

4.3 Fit Test Procedure

4.3.1. Have the subject put on the mask and perform a Fit Check. The subject should be allowed to wear the mask for at least five minutes, adjusting it as needed.

4.3.2. Place the hood on the subject, making sure that there is sufficient room for the subject to move his/her head from side to side and up and down without the mask touching the sides of the hood.

4.3.3. Instruct the subject to breathe through his/her mouth with tongue extended for the duration of the test and to report if the taste of the solution is detected at any time during the test.

4.3.4. Insert the nozzle of the Fit Test nebulizer into the hole at the front of the hood and spray 10, 20, or 30 squeezes into the hood, depending on which number was recorded from the Threshold Check.

4.3.5. Maintain the aerosol concentration in the hood throughout the test by squeezing one half the initial number of squeezes every 30 seconds into the hood.

4.3.6. Instruct the subject to perform the series of exercises below for 60 seconds each:

I. Normal Breathing

II. Deep Breathing

III. Turning head from side to side (pausing for a breath when head is to side)

IV. Moving head up and down slowly (pausing for a breath while head is up)

V. Talking (reading the enclosed "Rainbow Passage," reciting the alphabet, etc.)

VI. Jogging in Place

VII. Normal Breathing

4.3.7. If the exercises are completed without the subject tasting the aerosolized solution, then an acceptable fit has been demonstrated and the subject has passed the test.

4.3.8. If the subject reported tasting the aerosolized solution during the test, then the subject has failed to achieve an acceptable fit. The test subject should be allowed to re-test with the same model mask or with another model mask of his/her choice. Wait at least 15 minutes before re-testing and begin by repeating the Threshold Check.

4.4 Cleaning-Up

4.4.1. Rinse the nebulizers with warm water to prevent clogging. If clogging is found at the end of the test, clean the nebulizer and retest. The nebulizers should be thoroughly rinsed and refilled at least every four hours during testing.

4.4.2. Wipe out the inside of the hood with a damp cloth or paper towel to remove any solution residue. A disinfectant, such as isopropyl alcohol, may be used for cleaning to reduce potential contamination.